April 22, 2020

Implementation Dates for Transition to the Grifols Procleix Ultrieo Elite Assay on the Panther Testing Platform

Overview:

In July, all 5 CTS laboratories will convert from the current Grifols Ultrieo Plus NAT triplex assay (HIV 1/2, HBV and HCV), performed on the Tigris testing platform, to the newer Ultrieo Elite triplex assay, and performed on the Panther testing platform. The CTS Phoenix lab will implement first on July 7th, with the 4 remaining CTS labs located in Charlotte, Dallas, St. Louis and Tampa all implementing on July 13, 2020.

While the sample requirements for the Procleix Ultrieo Elite assay remain the same as Ultrieo Plus, however the package insert has been updated to reflect the assay performance on the newer Panther System. Additionally, the assay license number has not changed. The new package insert, updated interpretation information sheets, assay history list, and platform history list will be available on the CTS website beginning on July 7, 2020.

The Procleix Ultrieo Elite assay is a qualitative in vitro nucleic acid amplification test to screen for, hepatitis C virus (HCV) RNA, hepatitis B virus (HBV) DNA, and human immunodeficiency virus types 1 (HIV-1) and 2 (HIV-2) RNA in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, source plasma, and from other living donors.

Impact to Clients:

- The new Ultrieo Elite assay package insert, assay history list and platform history list will all be available on the CTS website on July 7, 2020.
- Clients that receive confirmatory computer reports via email may notice that all “series names” have been removed.
- No change to sample requirements.
- No change to result format for Ultrieo Elite assay.
- No expected delay in testing during the implementation.

Client Action Required:

- Notify appropriate staff of updated documents on the CTS website.
- Evaluate any regulatory or vendor notifications that may be necessary.

Questions and Additional Information:
Please email your questions or requests for additional information to Claudia Barnett (cbarnett@mycts.org), Lindsey Houghton (lhoughton@mycts.org), or O’Dina Hurlburt (ohurlburt@mycts.org).